Statement on the Food and Drug Administration's
Interim Final Rule on Prior Notification of Imported Food
Under the Public Health Security and
Bioterrorism Preparedness and Response Act of 2002
Docket No. 2002N-0278

May 5, 2004

This statement is submitted by the Air Courier Conference of America (ACCA), in response to the *Federal Register* notice in which the Food and Drug Administration (FDA) reopens the comment period on its interim final rule requiring prior notification (PN) of imported food, as authorized under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Docket No. 2002N-0278. ACCA is the trade association representing the express delivery services industry; our members include large firms with global delivery networks, such as DHL Express, Federal Express, Purolator, TNT U.S.A. and UPS, as well as smaller businesses with strong regional delivery networks, such as International Bonded Couriers, Midnite Express and World Distribution Services. Together, our members employ approximately 510,000 American workers. Worldwide, ACCA members have operations in over 200 countries; move more than 20 million packages each day; employ more than 800,000 people; operate 1,200 aircraft; and earn revenues in excess of $50 billion annually.

In reopening its comment period, FDA reiterates its interest in "exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as CBP's Customs-Trade Partnership Against Terrorism (C-TPAT)," as well as other flexible alternatives. As elaborated below, ACCA believes the C-TPAT status of its members, together with the express industry's status as the most automated, secure mode of transport, warrants flexible treatment for food shipments arriving via express consignment operators. Our comments also detail the types of flexible arrangements we believe are appropriate for the express industry.

By way of introduction, express consignment operators operate under special provisions established by the Bureau of Customs and Border Protection (CBP) and detailed in Part 128 of CBP's regulations (19 C.F.R. 128). Briefly, in order to have such facilities approved by Customs, express consignment operators must demonstrate that the services they provide are under "closely integrated administrative control." In large part, this means that the express consignment company must demonstrate that it exercises a "high degree of control" over the shipments in its custody. In order to meet Customs and industry specifications, express consignment operators have invested tens of millions of dollars to construct and operate dedicated sorting facilities that use state-of-the-art automation and scanning equipment.

Furthermore, express consignment operators are certified partners in security with CBP through the Customs-Trade Parnership Against Terrorism (C-TPAT). As members of this program, we are required by CBP to maintain supply chain integrity. We also maintain a range

of other security protocols at our facilities, including background checks of employees, controlled access to our facilities, and internal security staff. As a matter therefore of both industry practice (described in our previous comments) and CBP regulatory requirements, the risk of diversion of a shipment in the possession of an ACCA member is extremely low.

Unfortunately, in its interim final rule, the FDA has failed to distinguish the unique role played by express consignment operators from other affected industries. This "one-size fits all" approach will not help the FDA respond to a public health emergency or otherwise improve the nation's security. As detailed in our earlier submission of December 23, 2003, ACCA is concerned about certain aspects of the PN interim rule which we believe will have serious adverse consequences for the express industry and the consumers we serve, without achieving the desired national security benefit. ACCA and its members support the Act's goal of improving the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. We believe, however, that the FDA's implementation efforts misconstrue Congressional intent and will impose overly burdensome requirements on the express consignment industry that will not improve border security or enhance the FDA's ability to respond to public health emergencies.

We have three overriding concerns about the PN interim final rule: first, it requires that prior notice be provided a certain number of hours before the articles arrive at the first U.S. port of arrival, rather than the port where Customs entry is made; second, it does not adequately distinguish between shipments intended for consumption in the United States and shipments that simply transit the United States; and third, it does not contain a de minimis exemption for all low value shipments. In addition, we have experienced problems using FDA's website to obtain PN and believe the website problems should be addressed before any enforcement activity begins. Finally, we are concerned that, even though FDA might make significant changes to the interim final rule, these changes will not be published in the *Federal Register* prior to Phase III of the rule's implementation and enforcement period. Express companies may therefore be subject to enforcement actions and needless capital expenditures. These issues are discussed in detail below.

Port of arrival vs. port of entry

In many cases, express shipments are not entered for consumption at their port of arrival in the United States. Instead, they are moved under bond to an inland port where we maintain our express facilities. In these cases, the shipment is not released until Customs clearance is obtained -- that is, the shipment remains under the control of the express carrier until Customs clearance is obtained. We believe the security of our supply chain negates any diversion risk that FDA may be addressing by requiring presentation of PN at the port of arrival. Therefore, ACCA urges FDA to clarify in its final rule that, for express companies operating under Part 128 of Customs' regulations, PN be provided at the port of entry. It should be noted that express operators would still provide advance cargo information at the port of arrival, consistent with CBP regulations. This would enable CBP to screen and target shipments at the port of arrival using CBP's existing targeting rules - allowing CBP to utilize its experience and technology to

screen all shipments and not just those manifested as “food” products. . The PN data can then be screened at the consumption entry port where the facilities as well as the CBP and FDA processes and personnel exist to resolve any discrepancies.

Transit shipments

FDA’s interim final rule does not adequately distinguish between shipments intended for consumption in the United States and shipments that simply transit the United States. ACCA believes that PN should not be required for shipments that are not intended for U.S. consumption and, thus, that all foreign-to-foreign transits should be exempt from PN requirements. We believe this is a fair interpretation of Section 307 of the Bioterrorism Act, which identifies those food products subject to PN in the following manner: "In the case of an article of food that is being imported or offered for import into the United States, the Secretary...shall by regulation require, for the purposes of enabling such article to be inspected at ports of entry into the United States, the submission for the Secretary of a notice providing the identity of each of the following..." A shipment transiting the United States en route from a foreign origin to a foreign destination is not "imported or offered for import into the United States;" the mere landing on US soil or within port boundaries does not qualify a shipment as being imported. As we noted earlier in our comments, at least in the case of transit shipments handled by express consignment operators, there should be no concerns about diversion because they remain in the control of the express operator throughout their transit.

Furthermore, foreign shippers and foreign consignees are not going to know when to submit the required PN data because they do not know that their shipments transit the United States, as express carriers do not share the flight routes of their packages due to security concerns. In fact, we are advised by both TSA and CBP not to share such information with our customers for security reasons. Under the FDA’s interim final rules, however, ACCA members would have to contact these customers to provide appropriate PN data, making the customers aware of express carrier routes. There will also be delays in obtaining PN due to international time zone differences and language barriers. Additionally, the food will have to be off-loaded at the first port of arrival, most likely resulting in commercial gridlock.

To avoid these problems, ACCA urges FDA to clarify that PN data is not required for foreign-to-foreign shipments that transit the United States and remain under the control of an express consignment operators during their transit.

Low-value shipments

Third, the FDA’s interim final rule does not contain a de minimis exemption for all low value shipments. While the interim final rule does exempt certain personal use quantities (i.e., food for personal use that accompanies an individual arriving in the United States and food that was made by an individual in their personal residence and sent by that individual to the United States as a gift), it fails to cover all low value (e.g., less than $200) shipments for personal use or gifts.

ACCA urges that the FDA exempt from its final rule all shipments below $200. This will make the rule consistent with Customs' existing *de minimis* exemption.

Programming issues

ACCA urges FDA to address some programming shortcomings that have characterized its Prior Notice Systems Interface (PNSI) since its inception December 12. PNSI's response time is quite slow, creating significant delays for filers, and the system itself is down roughly two hours per week during peak daytime hours. Furthermore, the system slows down considerably in the afternoon. It can take as long as five minutes to move between the many screens needed to enter the PN information. In fact, slow response time is a daily occurrence. This significantly affects our ability to process PNs - we could probably process many more PNs daily if the system ran at a faster speed. Recently (i.e., March 11-13), the Existing Web Entry and Existing Prior Notice sections of the system were down, preventing ACCA members from accessing existing information to alleviate duplicate key entry. Consequently, our ability to input more PNs was hampered. It is often difficult to log onto the system - it sometimes takes several tries just to gain access to PNSI. And, once on, the system often times out on the user. This is especially a problem when entering more than one PN for a particular shipment. Even though someone is actively entering information, the system times out and logs him out in the middle of the transaction.

In addition, PNSI sometimes requires data beyond that needed for PN. For example, for shipments of wine, the system requires information regarding how the bottles were sterilized, whether the bottles are clear or colored, etc. PNSI should only require data needed for PN. Finally, PNSI is apparently programmed only in English. Given that FDA is requiring PN for shipments from anywhere in the world, it would seem sensible to program the system in languages other than English.

ACCA urges FDA to upgrade its systems to coincide with normal commercial flow times. Furthermore, FDA may want to consider the approach used by the Census Bureau, i.e., providing a range of automated filing options for meeting electronic SED (AES) filing requirements. Census offers an Internet application, a direction link for certified filers, and a PC-based application. In other words, Census recognizes that one shoe does not fit all.

Timing of changes to FDA's rule

As mentioned earlier, ACCA is concerned that, even though FDA might make significant changes to the interim final rule, these changes will not be published in the *Federal Register* prior to Phase III of the rule's implementation period. Therefore, express companies may be in the ironic position of being subject to enforcement actions on provisions that FDA ultimately modifies. Furthermore, this would mean that ACCA members would need to hire and train personnel in order to comply with a regulation for only a few months - and then the reasons for the new jobs would disappear, creating considerable dislocation.

Therefore, we urge FDA to issue written clarifications to its PN requirements for port of arrival, transit shipments and low-value shipments for express consignment operators prior to Phase III of the implementation period.

Conclusion

Again, ACCA and its members support the goal of the Bioterrorism Act and the FDA's implementation efforts. We believe that the unique nature of our operations allows us to address FDA's concerns in ways that differ from the requirements of FDA's interim final rule, and we urge FDA to revise its PN provisions as discussed above. For more information on this statement, please contact Sue Presti, Executive Director, Air Courier Conference of America, International, 6309 Beachway Drive, Falls Church, Virginia 22044 (telephone: 703-998-7121).